UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,042	04/27/2001	Filippo Belardelli	0508-1105	1462

466 7590 06/29/2007

YOUNG & THOMPSON
745 SOUTH 23RD STREET
2ND FLOOR
ARLINGTON, VA 22202

EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
06/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/845,042
Filing Date: April 27, 2001
Appellant(s): BELARDELLI ET AL.

Andrew J. Patch and Philip DuBois
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/25/06 appealing from the Office action mailed 4/10/06.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The amended summary of claimed subject matter filed 2/09/07 is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The rejection of Claims 54, 55, 57, 58, 61-63, 66, 67, and 69-81 under the first paragraph of 35 U.S.C. § 112 for lack of enablement have been withdrawn.

The rejection of Claims 75 and 79-81 under the first paragraph of 35 U.S.C. § 112 for inadequate written description for the introduction of new matter into the claims for the recitation of "TM-CSF" and "CM-CSF", respectively, has also been withdrawn.

The appellant's statement of the other grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 54, 55, 57, 58, 61-63, 66, 67, and 69-81 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a rejection for inadequate written description for the introduction of new matter into the claims.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) A process … in the absence of IL-4 … for a maximum of 3 days … (Claims 54, 63).

B) A process … in the absence of added IL-4 … for a maximum of 3 days … collecting cells within 3 days (Claim 69).

C) … IFN is present in a concentration range of 500-10,000 IU/ml (Claims 57 and 63, **note**: Claim 57 was improperly amended, i.e., the change was not shown on the Claim).

D) … GM-CSF at a concentration range of 500-1000 IU/ml (Claims 61 and 63).

F) The characteristics recited in Claims 72-81 as applied to DCs … for a maximum of 3 days (Claim 72) or within 3 days (Claims 72-76).

Regarding A-D), no support has been provided and none has been found. Applicant argues in response to a previous rejection that the term "in the absence of IL-4" or "in the absence of added IL-4" is implicitly supported by the specification. It remains the Examiner's position that "implicit" support is insufficient.

Regarding F), the characteristics refer to dendritic cells or mature dendritic cells, but not the partially mature dendritic cells disclosed at page 5 of the specification, i.e., the cells provided within 3 days. Further note that the experiments cited in support of the new claims comprised a duration of 3 days and not within 3 days or a maximum of 3 days.

(10) Response to Argument

Appellant argues, "the method of claims 54, 63 and 69 performed "in the absence of IL-4" is well-supported by the disclosure appearing for example at pages 19-39 of the specification".

It is noted that appellant does not attempt to cite a specific disclosure of the specific negative limitation of the claims because no where in the specification is this negative limitation specifically disclosed. While some experiments, comprising specific conditions, are performed without using IL-4, these experiments comprise insufficient support for the generic method of the instant claims that now specifically excludes the use of IL-4 in all methods encompassed by the instant claims.

Appellant argues, "the maximum three day culture time is abundantly supported by the specification as filed".

In support of the recitation of "for a maximum of 3 days" Appellant is only able to cite the term "within 3 days of culture", and then only from the Summary of the Invention section of the specification and once at page 18 of the specification. Appellant's cites at pages 9 (multiple), 10 (multiple), 11, 12 (multiple), 14, 15, 26, (multiple), and 28 disclose a culture period of 3 days, i.e., not a range of days. Regarding the cite at page 18, the cite at lines 16-17, "maintained within three days", makes no grammatical sense, but the next paragraph, lines 19 and 20, disclose that the time period for recovery of cells is "between day 2 and day 3". A

time period of "between day 2 and day 3" clearly is not commensurate in scope with a time period of "a maximum of 3 days", which would obviously include day 1. Thus, neither the terms "for a maximum of 3 days" or "within 3 days" are adequately supported by the instant specification. Indeed, it is clear that the method envisioned and exemplified by the instant specification is a method of culture lasting 3 days.

Appellant argues that the term "maximum" was introduced into the claims to overcome a prior art rejection. Appellant argues, "it is noteworthy that the term "maximum" was introduced by amendment because the recitation of culturing for three days was considered in a previous official action to read on the longer 5-7 day culture times of the prior art. Upon amending the claims as supported by the disclosure to avoid that overbroad reading, the present new matter rejection was then applied".

Appellant fails to note that the issue was actually the recitation of "comprising" culturing for three days which does indeed encompass culture periods of longer than three days. Regardless, while the introduction of new matter into claims may overcome prior art, it still may raise the issue of inadequate written description.

Appellant argues "the concentration range of "500-10,000 IU/ml" of type I IFN in claims 57 and 63, is clearly adequately supported by the specification for example at page 6, lines 8-12", citing ranges of 400-10,000 IU/ml and 500-2,000 IU/ml. Appellant further cites *In re Wertheim et al.*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976).

Clearly, the recited range of 500-10,000 IU/ml of type I IFN is not disclosed in the instant specification, thus, appellant attempts to rely on case law. However, other case law besides *In re Wertheim* applies here. For example, see *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 227 USPQ 177 (Fed. Cir. 1985) wherein the court held that written description cases must be decided on a case-by-case basis. Further, the court held that when critical limitations, in this instance limiting ranges to overcome enablement issues, are recited, actual written description of said limitations itself becomes a critical issue. See also *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991) where the court warned against the misapplication of precedents because of the fact-sensitive nature of the written description issues. Finally see *In re Smith* 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05 for the teaching that a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads.

Appellant cite the range of 250-1000 IU/ml GM-CSF in support of the claimed range of 500-1000 IU/ml of GM-CSF.

As set forth in the previous paragraph, a subgenus is not necessarily described by a genus encompassing it.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,
G.R. Ewoldt, Ph.D.

6/19/09
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER

Conferees:
Christina Chan

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Larry R. Helms, Ph.D.

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER